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I think we did everything we should have done for an influential document

**I think what we did was sufficient for an influential document. Here are some salient excerpts from the Peer review handbook.**

## **B-26**

### **II. Peer Review of Influential Scientific Information.**

1. **In General:** To the extent permitted by law, each agency shall conduct a peer review on all influential scientific information that the agency intends to disseminate. Peer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality.
2. **Adequacy of Prior Peer Review:** For information subject to this section of the Bulletin, agencies need not have further peer review conducted on information that has already been subjected to adequate peer review. In determining whether prior peer review is adequate, agencies shall give due consideration to the novelty and complexity of the science to be reviewed, the importance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed.
3. **Selection of Reviewers:**
  - a. **Expertise and Balance:** Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.
  - b. **Conflicts:** The agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable federal ethics requirements; (ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences policy for committee selection with respect to evaluating the potential for conflicts (e.g., those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income). For scientific information relevant to specific regulations, the agency shall examine a reviewer's financial ties to regulated entities (e.g., businesses), other stakeholders, and the agency.
  - c. **Independence:** Peer reviewers shall not have participated in development of the work product. Agencies are encouraged to rotate membership on standing panels across the pool of qualified reviewers. Research grants that were awarded to scientists based on investigator-initiated, competitive, peer-reviewed proposals generally do not raise issues as to independence or conflicts.

1. Choice of Peer Review Mechanism: The choice of a peer review mechanism (for example, letter reviews or ad hoc panels) for influential scientific information shall be based on the novelty and complexity of the information to be reviewed, the importance of the information to decision making, the extent of prior peer review, and the expected benefits and costs of review, as well as the factors regarding transparency described in II(5).
2. Transparency: The agency -- or entity managing the peer review -- shall instruct peer reviewers to prepare a report that describes the nature of their review and their findings and conclusions. The peer review report shall either (a) include a verbatim copy of each reviewer's comments (either with or without specific attributions) or (b) represent the views of the group as a whole, including any disparate and dissenting views. The agency shall disclose the names of the reviewers and their organizational affiliations in the report. Reviewers shall be notified in advance regarding the extent of disclosure and attribution planned by the agency. The agency shall disseminate the final peer review report on the agency's website along with all materials related to the peer review (any charge statement, the peer review report, and any agency response). The peer review report shall be discussed in the preamble to any related rulemaking and included in the administrative record for any related agency action.
3. Management of Peer Review Process and Reviewer Selection: The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

#### **From the body of the handbook:**

##### **2.5.3 What Should Be in the Peer Review Record?**

The peer review record should include all materials considered by the individual peer reviewers, the peer review report, and other input. Such materials include, at a minimum (see also Section 4.3.1):

- a) The draft work product submitted for peer review;
- b) Materials and information (including the charge) given to the peer reviewers;
- c) The peer review report, which summarizes the peer review findings and contains information about the peer reviewers (such as reviewers' names, affiliations, and a statement concerning potential conflicts and their resolution, if applicable);
- d) Logistical information about conduct of the peer review (such as times and locations of meetings);
- e) A memorandum, or other written record, approved by the Decision Maker, responding to the peer review comments specifying acceptance or, where thought appropriate, rebuttal and non-acceptance. The Office should prepare a written response to the peer review report addressing each comment.
- f) The final work product.

##### **2.5.4 How and When Should You Develop and Post Peer Review Reports and Agency Responses for Influential Scientific Information and Highly Influential Scientific Assessments?**

Offices are expected to make peer review reports of the influential scientific information and highly

influential scientific assessments publicly available to implement the provisions of the OMB Bulletin. Offices should instruct peer reviewers to prepare a report that describes the nature of their review and the nature of their findings and conclusions. The peer review report should either (a) include a verbatim copy of each reviewer's comments (either with or without specific attributions) or (b) represent the views of the group as a whole, including any disparate and dissenting views, although attribution of comments to names is not necessary. The names of the reviewers and their organizational affiliations should be included in the report. For highly influential scientific assessments, the report should also include the charge to the reviewers and a short paragraph on both the credentials and relevant experiences of each peer reviewer.

EPA will post or provide a link to the peer review reports on the Science Inventory website (<http://cfpub.epa.gov/si/>) along with all materials related to the peer review (charge statement and Agency response). The credibility of the final work product is likely to be enhanced if the public understands how the Agency addressed the specific concerns raised by the peer reviewers. Offices should consider preparing a written response for inclusion in the peer review report. For highly influential scientific assessments, the OMB Bulletin explicitly calls for Offices to prepare a written response to the peer review report explaining (a) the agency's agreement or disagreement with the views expressed in the report, (b) the actions that have or will be undertaken to respond to the report, and (c) the reasons the Office believes those actions satisfy any key concerns or recommendations in the report. These responses will also be posted on the Science Inventory website.

#### **2.5.5 What Should You Do with a Peer Review Record That Pertains to a Rulemaking Action?**

The Peer Review Leader should coordinate with his/her program's docket office to see that proper docketing procedures are followed for a peer review of a work product supporting a rule. If EPA relies on influential scientific information or a highly influential scientific assessment to support a regulatory action, the preamble should include a discussion of how EPA implemented the provisions of the OMB Bulletin. See Appendix C for a template to use for this purpose.

#### **4.3.1 Are Internal Peer Review Comments Included in the Peer Review Record?**

To be considered a legitimate peer review, internal EPA peer reviews should be formally conducted and documented. Such a process would be consistent with the guidance found in this Handbook for planning, conducting, and completing a peer review. When you follow this formal process to obtain peer review from EPA peers (see Section 1.5.9), then the whole record of that internal peer review should be included in the peer review record. This includes all the materials detailed in Section 2.5.3 (also see Section 4.3.1). Conducting a formal internal peer review is not the same thing as informal input from your EPA colleagues (i.e., "colleagues down the hall"), nor peer input from Agency personnel helping to develop the work product, nor organizational review and clearance processes. Such inputs from these informal processes should not be placed in the peer review record. The peer review record should contain only the information obtained when you conduct a formal internal peer review.